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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/003,481	10/25/2001	John C. Vellingner	AA206/98001	4356

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EXAMINER
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BEISNER, WILLIAM H

ART UNIT	PAPER NUMBER
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1744

DATE MAILED: 04/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/003,481

Applicant(s)

VELLINGER ET AL.

Examiner

William H. Beisner

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 17 January 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 4-7, 9-22, 24-26 and 28-37 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 4-7, 9-22, 24-26 and 28-37 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 January 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Drawings***

1. The drawings were received on 1/17/2006. These drawings are acceptable.

### ***Claim Objections***

2. Claims 17, 25 and 26 are objected to because of the following informalities:

Claim 17 has been amended such that it does not depend from any claim. The claim will be examined on its merits as though it depends from claim 4.

Claim 25 depends from cancelled claim 23. This claim will be examined on its merits as though it depends from claim 20.

Claim 26, last paragraph, "fr" should be --for--.

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 2-7, 9-22, 24-26 and 28-37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 4, "said upper collector plate" and "said lower collector plate" lack antecedent basis. Additionally, if the first or upper collector plate is stationary, then how can it be rotated are required of the "means for rotating"? Additionally, it is not clear how the first and second

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collector plates provide the recited functions of cell sampling, dilution and fixation in the absence of additionally positively recited structure.

In claim 7, “said upper collector plate” and “said lower collector plate” lack antecedent basis. Additionally, if the first or upper collector plate is stationary, then how can it be rotated are required of the “means for rotating”?

With respect to claim 12, it is not clear how the claimed device can provide the intended function or means for cell sampling, dilution and fixation in the absence of a positively recited structure for providing the function.

In claim 14, “said upper collector plate” and “said lower collector plate” lack antecedent basis. Additionally, if the first or upper collector plate is stationary, then how can it be rotated are required of the “means for rotating”?

In claim 26, “said upper collector plate” and “said lower collector plate” lack antecedent basis. Additionally, if the first or upper collector plate is stationary, then how can it be rotated are required of the “means for rotating”?

### ***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 4, 9-12, 15-19 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Knazek et al.(WO 90/02171) in view of Goffe (US 5,882,918) and either of Barbera-Guillem et al.(US 2002/0110905) or Woolner (GB 1 562 686).

The reference of Knazek et al. discloses a bioreactor apparatus that includes a cylindrical reactor vessel (11) that includes two cover plates, fill ports (13a, 13b, 15a, 15b) and a polymeric filter (12) (See page 21, lines 4-14). The apparatus includes a length of permeable tubing (18) and a pump (24), a fresh medium storage container (150), a sample collection container (160) that includes pinch valves (See page 13, lines 6-20). The device when used in an incubator

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device includes a device for controlling humidity (See page 18, lines 19-28) and is sealed within the external housing of the incubator device. The apparatus also includes a controller (80) with an electrical power source located outside the incubator enclosure (See page 19, lines 28-34).

With respect to the claimed “rotary sample collector”, in the absence of further positively recited, sample collection chamber (160) is considered to meet this claim language since it includes a cap (161) that can be rotated.

Claim 4 first differs by reciting that the reactor vessel includes rotary unions.

The reference of Goffe discloses that it is known in the art to rotate a hollow fiber reaction vessel that is held within an incubation enclosure by rotating the vessel (See column 5, lines 15-49).

In view of this teaching, it would have been obvious to one of ordinary skill in the art to rotate the vessel of the primary reference so as to agitate the vessel as suggested by the reference of Goffe. When employing complete 360 degree rotation as suggested by Goffe, it would have been obvious to provide the vessel with rotary unions for the known and expected result of allowing the medium to communicate with the vessel during the rotation of the vessel.

Note the controller of the system of the primary reference is capable of being programmed in view of the use of a microprocessor to control the system (See page 26, lines 14-34).

With respect to the claimed use of a bag rather than a bottle as a container for the medium, the primary reference recognizes that other known culture containers can be used in place of the disclosed bottles (See page 26, lines 27-33). As a result, it would have been obvious

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to one of ordinary skill in the art to employ a bag rather than a bottle for the known and expected result of providing an alternative means recognized in the art to achieve the same result.

With respect to the claimed rotary sample collector system of claim 4, the references of Barbera-Guillem et al. and Woolner both disclose that it is conventional in the art to employ motor operated rotary plate devices for collection of samples over a period of time (See Figure 8 of Barbera-Guillem et al. and Figures 1 and 2 of Woolner).

In view of either of these teachings, it would have been obvious to one of ordinary skill in the art to employ any of the art recognized sample collectors for the known and expected result of providing a means for automated sample collection over a period of time as is required of the modified primary reference.

With respect to claim 9, the reference of Knazek et al. discloses the use of permeable tubing (18) and a pump (24). With respect to the use of peristaltic pumps, while the primary reference is silent as to the use of these pumps, in the absence of a showing of criticality and/or unexpected results, it would have been obvious to one of ordinary skill in the art to employ peristaltic pumps within the system of the primary reference for the known and expected result of providing an art recognized means for flowing media within a culture system while minimizing the contact of the media with the pumping device.

With respect to claim 10, in the absence of further positively recited structure, the filter of the reference of Knazek et al. is considered to meet the claim limitation "low pressure drop" since the device is capable of removing just medium and/or medium and cells from the different outlet ports of the device.

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With respect to claim 11 and use of a bag rather than a bottle as a container for the medium, the primary reference recognizes that other known culture containers can be used in place of the disclosed bottles (See page 26, lines 27-33). As a result, it would have been obvious to one of ordinary skill in the art to employ a bag rather than a bottle for the known and expected result of providing an alternative means recognized in the art to achieve the same result.

With respect to claim 12, when using a plurality of sample collectors as suggested above, it would have been obvious to one of ordinary skill in the art to provide manifolding and valves for controlling the flow of medium to the plurality of collection bags.

With respect to claims 15 and 37, the permeable tubing (18) of Knazek et al. provides oxygenation of the medium within the reactor vessel.

With respect to claim 16, the use of pH, glucose and oxygen sensors with bioreactors is notoriously well known in the art and would have been obvious for the known and expected result of maintaining culture conditions that ensure efficient culturing conditions and cell viability.

With respect to claim 17, the rotary device of the references of Barbera-Guillem et al. and Woolner both employ motors. If not inherently disclosed, the use of such motors is entirely within the purview of one having ordinary skill in the art.

With respect to claim 18, the reference of Knazek et al. discloses the use of a polymeric filter (12) (See page 21, lines 4-14).

With respect to claim 19, statements of intended use carry no patentable weight in apparatus-type claims.



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9. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Knazek et al.(WO 90/02171) in view of Goffe (US 5,882,918) and either of Barbera-Guillem et al.(US 2002/0110905) or Woolner (GB 1 562 686) taken further in view of Pickering (US 4,161,172).

The combination of the references of Knazek et al. and Goffe with either Barbera-Guillem et al. or Woolner has been discussed above.

While the primary reference discusses the use of a humidity control device, the reference is silent as to the structure of the device.

The reference of Pickering discloses that it is known in the art to provide an incubator device with a humidifier that includes a water-saturated sponge (See column 11, lines 47-51).

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the incubator of the primary reference with a humidifier as disclosed by the reference of Pickering for the known and expected result of providing a means recognized in the art for stabilizing the humidity within an incubator device.

***Allowable Subject Matter***

10. Claims 5-7, 14, 20-22, 24-26 and 28-36 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, first and second paragraph, set forth in this Office action.

11. The following is a statement of reasons for the indication of allowable subject matter:

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Claims 5-7, 14, 26 and 28-36 would be allowable because the prior art of record fails to teach or fairly suggest the combination of the elements recited in these claims with a sampling system as recited in claims 5, 6, 7, 14 and 26 wherein the sampling system includes a plurality of sample retaining chambers and filters with a rotary inlet port and wherein the sampling system is capable of collecting cells on the filter, fixing the cells and storing the cells.

Claims 20-22, 24 and 25 would be allowable because the prior art fails to teach or fairly suggest the observation system of claim 20 in combination with the structure encompassed by the language of claim 4.

### ***Response to Arguments***

12. Applicant's arguments, see pages 14-17, filed 1/17/2006, with respect to the rejection(s) of claim(s) 4-7, 9-17, 19-21, 24, 26, 28-29 and 31-36 under 35 USC 112, second paragraph, 103 have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, in view of Applicants' amendments to the claims, a new ground(s) of rejection is made in view of the combination of the references of Knazek et al.(WO 90/02171) in view of Goffe (US 5,882,918) and either of Barbera-Guillem et al.(US 2002/0110905) or Woolner (GB 1 562 686). Additionally, new grounds under 35 USC 112, second paragraph, have been made in response to the amendments made to the claims.

### ***Conclusion***

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13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Beisner whose telephone number is 571-272-1269. The examiner can normally be reached on Tues. to Fri. and alt. Mon. from 6:15am to 3:45pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gladys J. Corcoran can be reached on 571-272-1214. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



William H. Beisner  
Primary Examiner  
Art Unit 1744

WHB